

Test Procedure for §170.304 (i) Exchange Clinical Information and Patient Summary Record

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules¹ to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document² is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010.*)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.304(i) Exchange clinical information and patient summary record.

- (1) Electronically receive and display. Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable

¹ Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

² Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

- implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted in the alternative standard, display it in human readable format.
- (2) Electronically transmit. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with:
- (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and
 - (ii) For the following data elements the applicable standard must be used:
 - (A) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);
 - (B) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and
 - (C) Medications. The standard specified in §170.207(d).

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the exchange clinical information and patient summary record certification criterion is discussed:

- "...compliance with this certification criterion can be achieved by demonstrating that the Complete EHR or EHR Module is capable of receiving and displaying patient summary records that comply with either patient summary record standard (and if the alternate standard is used, displaying the non-natively implemented patient summary record standard in human readable format) and generating and transmitting a patient summary record according to one of the patient summary record standards populated with the specified data types and their applicable standard(s)." "...we also expect that the Complete EHR designed to natively generate a CCD would be tested and certified as being capable of properly displaying any CCD that it receives and have added the term "display" in the beginning of the certification criterion."
- "For the purposes of electronically exchanging a patient summary record, we expect the patient summary record to include health information that is coded, where applicable, in accordance with adopted vocabulary standards. Therefore, unless otherwise required in the context of a meaningful use objective and measure, an eligible professional (or eligible hospital) would be permitted to map or crosswalk local/proprietary codes to the adopted vocabulary standards prior to transmitting a patient summary record."
- "Given the requests for additional clarity regarding the meaning of human readable format, we have decided to define the term in this final rule as follows: Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation (e.g., computer screen, handheld device, electronic document)."
- "...we do not require as a condition of certification that a specific transport standard be used to transmit a generated CCD."
- "To provide guidance and clarification to the industry, we will recognize any source vocabulary that is identified by NLM's RxNorm Documentation as a source vocabulary included in RxNorm. We are therefore revising the standard to state: "Any source vocabulary that is included in

RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.” We note that in section 3.1, of the most recent release of the “RxNorm Documentation (06/07/10, Version 2010-3),” NLM has identified the following source vocabularies as being included in RxNorm.

- GS - Gold Standard Alchemy
 - MDDDB - Medi-Span Master Drug Data Base
 - MMSL - Multum MediSource Lexicon
 - MMX - Micromedex DRUGDEX
 - MSH - Medical Subject Headings (MeSH)
 - MTHFDA - FDA National Drug Code Directory
 - MTHSPL - FDA Structured Product Labels
 - NDDF - First DataBank NDDF Plus Source Vocabulary
 - NDFRT - Veterans Health Administration National Drug File - Reference Terminology
 - SNOMED CT - SNOMED Clinical Terms (drug information)
 - VANDF - Veterans Health Administration National Drug File
- “We clarify for commenters that the standard we have adopted is a functional standard that enables the use of any source vocabulary that is included within RxNorm. Consequently, any one of these “source vocabularies” identified by NLM may be used, or any other source vocabulary successfully included within RxNorm.”

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

This test evaluates the capability for a Complete EHR or EHR Module to receive, display, generate and transmit patient summary records including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in the formats and vocabularies specified by the referenced standards. Per the FR criterion, the test procedure does not evaluate the capability to send and receive other types of patient information in the patient summary record. Since transport standards are not specified, the transmission portion of the test focuses on the ability to 1) generate a patient summary record and transfer it to an external conformance testing tool for verification of the patient summary instance, and 2) verify the ability to transmit the patient summary record using the transport technology defined by the Vendor.

The test procedure is organized into two sections:

- Receive and Display - evaluates the capability to receive and display (render) a patient summary record in the EHR when received in HL7 CCD format and when received in ASTM CCR format. The patient summary record includes diagnostic test results, problem list, medication list, and medication allergy list. Included in the test procedure is an evaluation of the capability of the EHR to display (render) in human readable format the received patient summary record that is formatted in the alternative standard

- The Tester sends to the EHR the NIST-supplied diagnostic test results, problem list, medication list, and medication allergy list test data in HL7 CCD format
 - Using Vendor-identified EHR functions, the Tester displays the received CCD test data and validates that the rendered data is complete and presented in human readable format.
 - The Tester sends to the EHR the NIST-supplied diagnostic test results, problem list, medication list, and medication allergy list test data in ASTM CCR format
 - Using Vendor-identified EHR functions, the Tester displays the received CCR test data and validates that the rendered data is complete and presented in human readable format
- Generate and Transmit– evaluates the capability to generate and transmit a patient summary record from the EHR in either HL7 CCD or ASTM CCR format as selected by the Vendor. The patient summary record includes diagnostic test results, problem list, medication list, and medication allergy list. Included in the test procedure is an evaluation of the capability to provide vocabulary coded values as defined by the referenced standards
 - Using Vendor-identified functions, the Tester enters the NIST-supplied diagnostic test results, problem list, medication list, and medication allergy list Test data into the EHR
 - The Tester generates the Patient Summary Record in the format selected by the Vendor (either HL7 CCD or ASTM CCR) and transfers it from the EHR to a NIST conformance test tool
 - Using Vendor-identified functions, the Tester transmits the Patient Summary Record to a receiving system (either a Tester’s receiving system or a vendor-identified system) using the Vendor-identified transport technology of the EHR. This may require configuration on the part of the Tester’s receiving system.
 - The Tester validates that the generated patient summary record is complete and in conformance
 - The Tester validates that the transmitted Patient Summary Record was transmitted by the EHR

For this portion of the test the medications test data will be evaluated for vocabulary conformance to the medications source vocabulary identified by the Vendor as implemented in the EHR. This may require a manual inspection of the test data in the patient summary record instance.

REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

Regulatory Referenced Standard

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) Patient summary record.

| §170.205 Content exchange standards and implementation specifications for exchanging electronic health information. | Regulatory Referenced Standard |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| (1) <u>Standard.</u> Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). <u>Implementation specifications.</u> The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299). | |
| (2) <u>Standard.</u> ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299). | |

| §170.207 Vocabulary standards for representing electronic health information. | Regulatory Referenced Standard |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information: | |
| (a) <u>Problems.</u> | |
| (1) <u>Standard.</u> The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions. | 45 CFR 162.1002(a)(1). (1) <i>International Classification of Diseases, 9th Edition, Clinical Modification, (ICD–9–CM), Volumes 1 and 2</i> (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (i) Diseases. (ii) Injuries. (iii) Impairments. (iv) Other health problems and their manifestations. (v) Causes of injury, disease, impairment, or other health problems. |
| (2) <u>Standard.</u> International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version (incorporated by reference in §170.299). | |
| (b) <u>Laboratory test results. Standard.</u> Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory (incorporated by reference in §170.299). | |

| §170.207 Vocabulary standards for representing electronic health information. | Regulatory Referenced Standard |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (c) <u>Medications. Standard.</u> Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine. | As of 6/10/2010 the following source vocabularies are listed by NLM: GS Gold Standard Alchemy MDDB Medi-Span Master Drug Data Base MMSL Multum MediSource Lexicon MMX Micromedex DRUGDEX MSH Medical Subject Headings (MeSH) MTHFDA FDA National Drug Code Directory MTHSPL FDA Structured Product Labels NDDF First DataBank NDDF Plus Source Vocabulary NDFRT Veterans Health Administration National Drug File - Reference Terminology SNOMED CT SNOMED Clinical Terms (drug information) VANDF Veterans Health Administration National Drug File |

NORMATIVE TEST PROCEDURES

Derived Test Requirements

- DTR170.304.i.1 – 1: Electronically Receive and Display HL7 CCD Patient Summary Record
- DTR170.304.i.1 – 2: Electronically Receive and Display ASTM CCR Patient Summary Record
- DTR170.304.i.2 – 1: Electronically Generate and Transmit HL7 CCD or ASTM CCR Patient Summary Record

DTR170.304.i.1 – 1: Electronically Receive and Display HL7 CCD Patient Summary Record

Required Vendor Information

- VE170.304.i.1 - 1.01: Vendor shall provide communications configuration information and patient identifiers necessary to send test patient summary records in HL7 CCD format to the EHR
- VE170.304.i.1 - 1.02: Vendor shall identify the EHR function(s) that are available to view an HL7 CCD formatted patient summary record in human readable format when received from an external source

Required Test Procedure

- TE170.304.i.1 - 1.01: Tester shall select patient summary record data from NIST-supplied test data in TD170.304.i
- TE170.304.i.1 - 1.02: Tester shall send the patient summary record to the EHR
- TE170.304.i.1 - 1.03: Using the EHR function(s) identified by the Vendor and the NIST-supplied Inspection Test Guide, the Tester shall display and verify that the patient summary record test data are displayed in the EHR, including
 - Diagnostic test results
 - Problem list
 - Medication list

- Medication allergy list

Inspection Test Guide

IN170.304.i.1 - 1.01: Using the data in the NIST-supplied Test Data TD170.304.i, Tester shall verify that the received patient summary record test data are complete, correct and viewable in the EHR in human readable format

DTR170.304.i.1 – 2: Electronically Receive and Display ASTM CCR Patient Summary Record

Required Vendor Information

VE170.304.i.1 - 2.01: Vendor shall provide communications configuration information and patient identifiers necessary to send test patient summary records in ASTM CCR format to the EHR.

VE170.304.i.1 - 2.02: Vendor shall identify the EHR function(s) that are available to view an ASTM CCR formatted patient summary record in human readable format when received from an external source

Required Test Procedure

TE170.304.i.1 - 2.01: Tester shall select patient summary record data from NIST-supplied test data in TD170.304.i

TE170.304.i.1 - 2.02: Tester shall send the patient summary record in ASTM CCR format to the EHR

TE170.304.i.1 - 2.03: Using the EHR function(s) identified by the Vendor and the NIST-supplied Inspection Test Guide, the Tester shall display and verify that the patient summary record test data are received in the EHR, including

- Diagnostic test results
- Problem list
- Medication list
- Medication allergy list

Inspection Test Guide

IN170.304.i.1 - 2.01: Using the data in the NIST-supplied Test Data TD170.304.i, Tester shall verify that the received patient summary record test data are complete, correct and viewable in the EHR in human readable format

DTR170.304.i.2 – 1: Electronically Generate and Transmit HL7 CCD or ASTM CCR Patient Summary Record

Required Vendor Information

VE170.304.i.2 – 1.01: Vendor shall identify the standard format they will use for this test (CCD or CCR)

VE170.304.i.2 – 1.02: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.304.i.2 – 1.03: Vendor shall identify the EHR function(s) available to 1) select the patient, 2) enter patient summary record data into the EHR, and 3) send the patient summary record data from the EHR to an external receiving system

VE170.304.i.2 - 1.04: Vendor shall identify the medications source vocabulary implemented within the EHR

Required Test Procedures

TE170.304.i.2 – 1.01: Tester shall select patient summary record test data from NIST-supplied test data in TD170.304.i

TE170.304.i.2 – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter the patient summary record test data

TE170.304.i.2 – 1.03: Using the EHR function(s) identified by the Vendor, the Tester shall send the patient summary record in the vendor-selected format to a NIST-supplied test tool as described in the Conformance Test Tools section of this test procedure

TE170.304.i.2 – 1.04: Using the NIST-supplied test tool and the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient summary record test data are transmitted correctly and without omission by the EHR, including

- Diagnostic test results
- Problem list
- Medication list
- Medication allergy list

TE170.304.i.2 – 1.05: Using the EHR function(s) identified by the Vendor, the Tester shall transmit the Patient Summary Record to an external receiving system using the Vendor-identified transport technology of the EHR. The receiving system may either be a Tester's receiving system that is configurable to use the transport technology of the EHR system or module, or a Vendor-identified system capable of receiving from the EHR system or module

Inspection Test Guide

IN170.304.i.2 – 1.01: Using the data in the NIST-supplied Test Data TD170.304.i, Tester shall verify that the patient summary record test data are entered into the EHR correctly and without omission

IN170.304.i.2 – 1.02: Tester shall verify that all of the patient summary record test data are stored in the patient's record, including

- Diagnostic test results
- Problems
- Medications
- Medication allergies

IN170.304.i.2 – 1.03: Tester shall verify that the patient summary record test data are sent to the NIST-supplied test tool by the EHR.

IN170.304.i.2 – 1.04: Using the NIST-supplied conformance testing tool identified in the Conformance Test Tools section of this test procedure, Tester shall verify that the transmitted patient summary record test data transmitted to the NIST-supplied test tool are

complete and correct, and that the received test data are conformant to the referenced content (CCD or CCR) and vocabulary standards. The Tester shall verify that the medications source vocabulary values map correctly to the RxNorm values supplied in the NIST test data. The vocabulary verification may require manual inspection of the data.

IN170.304.i.2 – 1.05: Tester shall verify that the Patient Summary Record was received by the external receiving system based on the transport technology and configuration necessary to communicate with the EHR system

TEST DATA

Test data is provided by NIST in this Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied test data focus on evaluating the basic capabilities required of EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data is formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the NIST-supplied test data during the test, without exception, unless one of the following conditions exist:

- The Tester determines that the Vendor product is sufficiently specialized that the NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the NIST-supplied test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The Test Procedures require that the Tester enter the test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully control the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

The format of the test data below is for readability purposes in this Test Procedure only. It does not represent an implementation of the 'display in human readable format' requirement of this Test Procedure. It is not intended to represent 'human readable' per the Final Rule definition. The format used below does not place any requirements on an EHR module or system. There are no additional requirements for the meaning of 'human readable' beyond those articulated in the definition of 'human readable' referenced above.

TD170.304.i.: Exchange clinical information and patient summary record

* indicates alternative standard code per certification criteria

Patient Summary Record Test Data – Set #1

Patient

| Name | Date/Time of Birth | Gender | Identification Number | Identification Number Type | Address/Phone |
|---------------|------------------------|--------|-----------------------|----------------------------|-------------------------------------------------------------------------|
| John D. Smith | 07/04/1960 10:15:02 | Male | 999999999 | Medical Record Number | 355 Maple Street Williamsport, Pennsylvania 17701 570-837-8364 |

“Source” for all data for this patient: John Fitzgerald, MD

Problem List

| Type | ICD-9 Code | Patient Problem | Status | Date Diagnosed |
|-----------|------------|-------------------------------|---------|----------------|
| Diagnosis | 250.02 | Diabetes Mellitus, Type 2 | Active | 09/16/2009 |
| Condition | 272.4 | Hyperlipidemia | Active | 05/05/2002 |
| Finding | 414.01 | Coronary Artery Disease (CAD) | Chronic | 05/05/2002 |
| Symptom | 401.9 | Hypertension, Essential | Active | 05/05/2002 |

| Type | SNOMED Code* | Patient Problem | Status | Date Diagnosed |
|----------|--------------|---------------------------|---------|----------------|
| Disorder | 44054006 | Diabetes Mellitus, Type 2 | Active | 09/16/2009 |
| Disorder | 55822004 | Hyperlipidemia | Active | 05/05/2002 |
| Disorder | 53741008 | Coronary Arteriosclerosis | Chronic | 05/05/2002 |
| Disorder | 59621000 | Essential Hypertension | Active | 05/05/2002 |

Medication List

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|----------------------|------------|----------|----------|-------|-----------|--------------|--------|
| 205875 | Medication | glyburide | Diabeta | 2.5 mg | 1 Tablet | PO | Q AM | 09/16/2009 | Active |
| 617314 | Medication | atorvastatin calcium | Lipitor | 10 mg | 1 Tablet | PO | Q Day | 05/05/2002 | Active |

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|--------------------|------------|----------|----------|-------|-----------|--------------|--------|
| 200801 | Medication | furosemide | Lasix | 20 mg | 1 Tablet | PO | BID | 05/05/2002 | Active |
| 628958 | Medication | potassium chloride | Klor-Con | 10 mEq | 1 Tablet | PO | BID | 05/05/2002 | Active |

Medication Allergy List

| Type | SNOMED Code | Medication/Agent | Reaction | Date Recorded |
|--------------|-------------|------------------|----------------------------|---------------|
| Drug Allergy | 293597001 | Codeine | Hives | 06/27/1996 |
| Drug Allergy | 294506009 | Ampicillin | Diarrhea, nausea, vomiting | 03/15/1994 |

Diagnostic Test Results

| Type | LOINC Code | Test (Normal Range) | Result | Date Performed |
|-----------|------------|--------------------------------------|-------------------------------------------------|----------------|
| Chemistry | 14771-0 | Fasting Blood Glucose (70–100 mg/dl) | 178 mg/dl | 09/16/2009 |
| Chemistry | 14682-9 | Creatinine (0.5–1.4 mg/dl) | 1.0 mg/dl | 09/16/2009 |
| Chemistry | 14937-7 | BUN (7–30 mg/dl) | 18 mg/dl | 09/16/2009 |
| Chemistry | 2951-2 | Sodium (135–146 mg/dl) | 141 mg/dl | 09/16/2009 |
| Chemistry | 2823-3 | Potassium (3.5–5.3 mg/dl) | 4.3 mg/dl | 09/16/2009 |
| Chemistry | 14647-2 | Total cholesterol (<200 mg/dl) | 162 mg/dl | 09/16/2009 |
| Chemistry | 14646-4 | HDL cholesterol (≥40 mg/dl) | 43 mg/dl | 09/16/2009 |
| Chemistry | 2089-1 | LDL cholesterol (<100 mg/dl) | 84 mg/dl | 09/16/2009 |
| Chemistry | 14927-8 | Triglycerides (<150 mg/dl) | 177 mg/dl | 09/16/2009 |
| Imaging | 24648-8 | Chest X-ray, PA | No disease is seen in the lung fields or pleura | 09/16/2009 |

Patient Summary Record Test Data – Set #2

Patient

| Name | Date/Time of Birth | Gender | Identification Number | Identification Number Type | Address/Phone |
|---------------|------------------------|--------|-----------------------|----------------------------|-------------------------------------------------------------|
| Ralph Johnson | 06/28/1984 13:20:10 | Male | 9813466798 | Medical Record Number | 355 Elm Street Morton, Illinois 61550 309-377-8365 |

“Source” for all data for this patient: Carl Roberts, MD

Problem List

| Type | ICD-9 Code | Patient Problem | Status | Date Diagnosed |
|-----------|------------|---------------------------|--------|----------------|
| Diagnosis | 493.00 | Asthma, unspecified | Active | 12/22/2009 |
| Diagnosis | 250.02 | Diabetes Mellitus, Type 2 | Active | 08/10/2008 |

| Type | SNOMED Code* | Patient Problem | Status | Date Diagnosed |
|----------|--------------|---------------------------|--------|----------------|
| Disorder | 195967001 | Asthma | Active | 12/22/2009 |
| Disorder | 44054006 | Diabetes Mellitus, Type 2 | Active | 08/10/2008 |

Medication List

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|------------------------|----------------------------|----------|----------|---------|-----------|--------------|--------|
| 206833 | Medication | metaproterenol sulfate | Alupent Inhalation Aerosol | 15 mg/ml | 2 Puffs | Inhaled | Q4h | 12/22/2009 | Active |
| 205875 | Medication | glyburide | Diabeta | 2.5 mg | 1 Tablet | PO | Q AM | 08/10/2008 | Active |

Medication Allergy List

| Type | SNOMED Code | Medication/Agent | Reaction | Date Recorded |
|--------------|-------------|------------------|---------------------------------------------|---------------|
| Drug Allergy | 91936005 | Penicillin | Rash and anaphylaxis | 08/10/2008 |
| Drug Allergy | 293620004 | Indomethacin | Nausea, vomiting, rash, dizziness, headache | 03/25/2003 |

Diagnostic Test Results

| Type | LOINC Code | Test (Normal Range) | Result | Date Performed |
|------------|------------|--------------------------------------|-------------------------------------------------------|----------------|
| Imaging | 24648-8 | Chest X-ray, PA | Increased bronchial wall markings, patchy infiltrates | 02/16/2010 |
| Chemistry | 14771-0 | Fasting Blood Glucose (70–100 mg/dl) | 70 mg/dl | 12/22/2009 |
| Hematology | 26449-9 | Eosinophil Count (1 – 3 %) | 2% | 12/22/2009 |
| Imaging | 24648-8 | Chest X-ray, PA | Bronchial wall markings | 12/22/2009 |

Patient Summary Record Test Data – Set #3

Patient

| Name | Date/Time of Birth | Gender | Identification Number | Identification Number Type | Address/Phone |
|--------------|------------------------|--------|-----------------------|----------------------------|----------------------------------------------------------------|
| Jane Andrews | 05/12/1955 09:30:15 | Female | 9639275266 | Medical Record Number | 355 1st Street Fargo, North Dakota 58104 701-366-8364 |

“Source” for all data for this patient: Robert James, MD

Problem List

| Type | ICD-9 Code | Patient Problem | Status | Date Diagnosed |
|-----------|------------|---------------------------------------|----------|----------------|
| Diagnosis | 486 | Pneumonia | Resolved | 01/22/2010 |
| Diagnosis | 496.0 | Chronic Obstructive Pulmonary Disease | Chronic | 10/10/1999 |

| Type | SNOMED Code* | Patient Problem | Status | Date Diagnosed |
|----------|--------------|----------------------------------|----------|----------------|
| Disorder | 233604007 | Pneumonia | Resolved | 01/22/2010 |
| Disorder | 13645005 | Chronic Obstructive Lung Disease | Chronic | 10/10/1999 |

Medication List

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|--------------|--------------|----------|----------|-------|-----------|--------------|------------------|
| 308460 | Medication | azithromycin | Azithromycin | 250 mg | 1 Tablet | PO | QD | 01/22/2010 | No Longer Active |

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|--------------------------------|-------------------|-------------|---------|---------|-----------|--------------|--------|
| 836370 | Medication | ipratropium bromide monhydrate | Atrovent Inhaler | 18 mcg/puff | 2 Puffs | Inhaled | QID | 10/10/1999 | Active |
| 630208 | Medication | albuterol sulfate | Albuterol Inhaler | 2.5 mg/3ml | 2 Puffs | Inhaled | Q 4 PRN | 10/10/1999 | Active |

Medication Allergy List

| Type | SNOMED Code | Medication/Agent | Reaction | Date Recorded |
|--------------|-------------|------------------|-------------------------|---------------|
| Drug Allergy | 91936005 | Penicillin | Rash and anaphylaxis | 06/10/2009 |
| Drug Allergy | 91939003 | Sulfonamides | Hives, photosensitivity | 04/25/1988 |

Diagnostic Test Results

| Type | LOINC Code | Test (Normal Range) | Result | Date Performed |
|------------|------------|--------------------------------------------------|---------------------------------------------------------------------------------------|----------------|
| Imaging | 42272-5 | Chest X-ray, PA & Lateral | Hyperinflated lungs with flattened diaphragm and central pulmonary artery enlargement | 02/15/2010 |
| Hematology | 718-7 | Hemoglobin (male: 14-18 g/dl female: 12-16 g/dl) | 16 g/dl | 12/22/2009 |
| Hematology | 4544-3 | Hematocrit (male: 40-54% female: 36-48%) | 45% | 12/22/2009 |
| Cardiology | 34534-8 | Electrocardiogram | Normal Sinus Rhythm | 12/22/2009 |

Patient Summary Record Test Data – Set #4

Patient

| Name | Date/Time of Birth | Gender | Identification Number | Identification Number Type | Address/Phone |
|--------------|------------------------|--------|-----------------------|----------------------------|------------------------------------------------------------------------|
| Sally Eckerd | 08/08/1962 18:25:59 | Female | 998877799 | Medical Record Number | 754 Samuel Street, Shawville, Pennsylvania 16873 814-645-2981 |

“Source” for all data for this patient: Mark Payne, MD

Problem List

| Type | ICD-9 Code | Patient Problem | Status | Date Diagnosed |
|-----------|------------|-------------------------|--------|----------------|
| Condition | 272.4 | Hyperlipidemia | Active | 07/05/2006 |
| Symptom | 401.9 | Hypertension, Essential | Active | 07/05/2006 |

| Type | SNOMED Code* | Patient Problem | Status | Date Diagnosed |
|----------|--------------|------------------------|--------|----------------|
| Disorder | 55822004 | Hyperlipidemia | Active | 07/05/2006 |
| Disorder | 59621000 | Essential Hypertension | Active | 07/05/2006 |

Medication List

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|----------------------|------------|----------|----------|-------|-----------|--------------|--------|
| 617314 | Medication | atorvastatin calcium | Lipitor | 10 mg | 1 Tablet | PO | Q Day | 07/05/2006 | Active |
| 200801 | Medication | furosemide | Lasix | 20 mg | 1 Tablet | PO | BID | 07/05/2006 | Active |
| 628958 | Medication | (potassium chloride | Klor-Con | 10 mEq | 1 Tablet | PO | BID | 07/05/2006 | Active |

Medication Allergy List

| Type | SNOMED Code | Medication/Agent | Reaction | Date Recorded |
|--------------|-------------|------------------|----------------------|---------------|
| Drug Allergy | 91936005 | Penicillin | Rash and anaphylaxis | 05/22/1998 |
| Drug Allergy | 293597001 | Codeine | Hives | 02/17/1992 |

Diagnostic Test Results

| Type | LOINC Code | Test (Normal Range) | Result | Date Performed |
|-----------|------------|--------------------------------|-----------|----------------|
| Chemistry | 2823-3 | Potassium (3.5–5.3 mg/dl) | 4.5 mg/dl | 07/15/2009 |
| Chemistry | 14647-2 | Total cholesterol (<200 mg/dl) | 180 mg/dl | 07/15/2009 |
| Chemistry | 14646-4 | HDL cholesterol (≥40 mg/dl) | 38 mg/dl | 07/15/2009 |
| Chemistry | 2089-1 | LDL cholesterol (<100 mg/dl) | 120 mg/dl | 07/15/2009 |
| Chemistry | 14927-8 | Triglycerides (<150 mg/dl) | 187 mg/dl | 07/15/2009 |

| Type | LOINC Code | Test (Normal Range) | Result | Date Performed |
|---------|------------|---------------------------|--------------------------------------------------------------------------------------------|----------------|
| Imaging | 42272-5 | Chest X-ray, PA & Lateral | The heart outline is normal and the hilar and mediastinal vessels are of normal appearance | 07/15/2009 |

Patient Summary Record Test Data – Set #5

Patient

| Name | Date/Time of Birth | Gender | Identification Number | Identification Number Type | Address/Phone |
|---------------|------------------------|--------|-----------------------|----------------------------|---------------------------------------------------------------|
| Matthew Brown | 09/22/1965 16:48:25 | Male | 988730987 | Medical Record Number | 754 Sharp Street Aurora, Colorado 80011 303-544-9988 |

“Source” for all data for this patient: Pamela Jones, MD

Problem List

| Type | ICD-9 Code | Patient Problem | Status | Date Diagnosed |
|-----------|------------|---------------------------|--------|----------------|
| Diagnosis | 250.02 | Diabetes Mellitus, Type 2 | Active | 07/17/2009 |
| Symptom | 401.9 | Hypertension, Essential | Active | 06/05/2008 |

| Type | SNOMED Code* | Patient Problem | Status | Date Diagnosed |
|----------|--------------|---------------------------|--------|----------------|
| Disorder | 44054006 | Diabetes Mellitus, Type 2 | Active | 07/17/2009 |
| Disorder | 59621000 | Essential Hypertension | Active | 06/05/2008 |

Medication List

| RxNorm Code | Product | Generic Name | Brand Name | Strength | Dose | Route | Frequency | Date Started | Status |
|-------------|------------|--------------------|------------|----------|----------|-------|-----------|--------------|--------|
| 205875 | Medication | glyburide | Diabeta | 2.5 mg | 1 Tablet | PO | Q AM | 07/17/2009 | Active |
| 200801 | Medication | furosemide | Lasix | 20 mg | 1 Tablet | PO | BID | 06/05/2008 | Active |
| 628958 | Medication | potassium chloride | Klor-Con | 10 mEq | 1 Tablet | PO | BID | 06/05/2008 | Active |

Medication Allergy List

| Type | SNOMED Code | Medication/Agent | Reaction | Date Recorded |
|--------------|-------------|------------------|----------------------------|---------------|
| Drug Allergy | 294506009 | Ampicillin | Diarrhea, nausea, vomiting | 03/25/1997 |
| Drug Allergy | 91939003 | Sulfonamides | Hives, photosensitivity | 04/25/1989 |

Diagnostic Test Results

| Type | LOINC Code | Test (Normal Range) | Result | Date Performed |
|-----------|------------|--------------------------------------|--------------------------------------------------------------------------------------------|----------------|
| Chemistry | 14771-0 | Fasting Blood Glucose (70–100 mg/dl) | 145 mg/dl | 07/17/2009 |
| Hemistry | 2823-3 | Potassium (3.5–5.3 mg/dl) | 4.5 mg/dl | 07/17/2009 |
| Chemistry | 14927-8 | Triglycerides (<150 mg/dl) | 187 mg/dl | 07/17/2009 |
| Imaging | 42272-5 | Chest X-ray, PA & Lateral | The heart outline is normal and the hilar and mediastinal vessels are of normal appearance | 07/17/2009 |

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- HL7 CCD/HITSP C32 – NIST provides an HL7 CCD/HITSP C32 validation tool designed specifically to support this test procedure. The tool is available in two forms:
 - a downloadable package for local installation available at <http://xreg2.nist.gov/cda-validation/mu.html>
 - a web-accessible validator which is hosted by NIST available at <http://xreg2.nist.gov/cda-validation/mu.html>

Support for these tools is available by contacting

[Andrew McCaffrey](mailto:andrew.mccaffrey@nist.gov) (andrew.mccaffrey@nist.gov)

Computer Scientist

National Institute of Standards and Technology (NIST)

Information Technology Laboratory

- ASTM CCR – Open Health Data provides an ASTM CCR validation tool designed specifically to support this test procedure. The tool is available through the following:
 - Files can be retrieved from the SourceForge site:
<http://sourceforge.net/projects/ccrvalidator>
 - Direct link to the file:
<http://sourceforge.net/projects/ccrvalidator/files/ValidationService/1.0/ValidationService-1.0.war/download>
 - Source code location:
<http://ccrvalidator.svn.sourceforge.net/viewvc/ccrvalidator/branches/>
- HL7 CCD style sheet – HL7 provides a style sheet to render HL7 CCD structured documents as part of the CCD specifications package. Contact HL7 directly for the specification package.

The following information is provided to assist the Tester in interpreting the conformance reports generated by the NIST conformance testing tools.

The HL7 CCD/HITSP C32 and ASTM CCR validation tools evaluate individual conformance statements which have been derived from the standards and implementation guides identified in the Final Rule and the test data provided in this test procedure. The validation tools evaluate the submitted CCD/CCR instance for each conformance statement, and then produce a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates general conformance to the standard and test data expectations. If reported, Errors should be considered as significant departures from the standard or test data requirements which need to be corrected in order to claim conformance. ATCBs will need to further analyze each error to determine if, in the context of meeting the criterion and overall meaningful use objective, the error results in a failure of the Test Procedure by the EHR technology. The tester may need to inspect test data values derived from required vocabularies and code sets.

Document History

| Version Number | Description | Date Published |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 0.7 | Original draft version | April 9, 2010 |
| 1.0 | Updated to reflect Final Rule | July 21, 2010 |
| 1.0 | Updates include: <ul style="list-style-type: none">• removed “Pending” from header• updated zip codes in test data | August 13, 2010 |